



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/727,123

12/02/2003

Raymond E. Ideker

5656.34

4773

7590

09/18/2007

Julie H. Richardson

Myers Bigel Sibley & Sajovec, P.A.

P.O. Box 37428

Raleigh, NC 27627

EXAMINER

BERTRAM, ERIC D

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

09/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/727,123
Filing Date: December 02, 2003
Appellant(s): IDEKER ET AL.

MAILED
SEP 14 2007
GROUP 3700

Laura M. Kelley
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/29/2007 appealing from the Office action mailed 11/24/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Claims 26-28, 41-43, 49 and 51 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,772,613 to Gelfand et al. ("Gelfand") in view of "Commotio cordis: sudden death due to chest wall impact in sports" by Link ("Link").

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,772,613	GELFAND ET AL.	6-1998
6,390,996	HALPERIN ET AL.	5-2002

Link, Mark S. "Commotio cordis: sudden death due to chest wall impact in sports" Heart, 81(2) Feb 1999, pp. 109-110.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 26-28, 41-43, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand et al. (US 5,772,613, hereinafter Gelfand) in view of Link ("Commotio cordis: sudden death due to chest wall impact in sports"). Gelfand discloses a method for performing chest compressions where an ECG instrument 123 is employed to sense the intrinsic spontaneous heart activity of a patient in real-time (Col. 9, lines 1-3). Based on this sensed activity, compression is applied using a CPR vest 102 that is timed to be delivered at a favorable time to improve cardiac function (Col. 9, lines 3-10). Gelfand does not disclose, however, identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle, and then compressing the heart during a non-vulnerable time based in the identifying. Attention is directed to the secondary reference of Link, which discloses that low energy chest wall blows may result in sudden death due to the initiation of ventricular fibrillation (VF). It is the Examiner's position that the compressions delivered during CPR would inherently be categorized as low energy chest wall blows. Link further discloses that only blows delivered specifically during the upslope of the T-wave result in VF (see Experimental models section). In

Art Unit: 3766

order to accomplish this, blows to the chest were timed with an intrinsic spontaneous cardiac cycle of a subject. Since VF was only induced during the T-wave of intrinsic spontaneous cardiac cycles, it is exceedingly apparent that low energy impacts to the chest wall should be avoided at all costs during this vulnerable period of the heart. Therefore, since Gelfand already teaches a method of timing compressions of the heart based on intrinsic spontaneous cardiac activity to improve cardiac function, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to time the compressions to avoid the vulnerable T-wave portion of the cardiac cycle, as suggested by Link, in order to avoid initiating VF in a subject.

Regarding claims 49 and 51, Gelfand, as modified above, discloses a method and apparatus completing all of the instructions contained in claims 49 and 51. Gelfand does not, however, specifically disclose the use of a computer-readable medium loaded with code containing the instructions. Although Gelfand does not disclose the medium, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to include the medium since it is old and well known that a processor cannot function without first being programmed by a medium containing the necessary instructions.

Claims 31-33, 44, 45, 52 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand in view of Link and further in view of Halperin et al. (US 6,390,996, hereinafter Halperin). Gelfand, as modified above, discloses the applicant's basic invention with the exception of using closed chest manual compression of the heart. While the use of closed chest manual compression is notoriously old and well

Art Unit: 3766

known in the art, attention is also directed to the secondary reference of Halperin, which discloses the use of closed chest manual compressions based on sensed ECG patterns (Col. 2, line 62-Col. 3, line 17). Halperin also discloses the use of an automated controller and automatic compression device, thus teaching that the use of manual compressions or automatic compressions is interchangeable when applying CPR. Therefore, since Halperin demonstrates that manual compressions and automatic compressions were art-recognized equivalents at the time of the applicant's invention for supplying CPR, one of ordinary skill in the art would have found it obvious to supply manual compressions instead of automatic compressions since they produce the same results.

Regarding claims 32 and 54-56, Gelfand, as modified, also does not disclose generating an audible alert when compression is to be initiated. However, Halperin discloses that the amplitude of an audible indicator may be delivered to coincide with the desired frequency of chest compressions (Col. 9, lines 20-28). Furthermore, the audible indicator is inherently configured to indicate when to start and when to stop compressions since a user would compress in time with the audible signals, and would stop compression when the audible signal ceased. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method of Gelfand by including an audible alert as taught by Halperin in order to prompt a user to manually compress the chest of a subject at the proper rate.

Regarding claims 52 and 57, the rejections applied above to similarly worded claims 32 and 52-56 apply here as well. Gelfand does not, however, specifically

Art Unit: 3766

disclose the use of a computer-readable medium loaded with code containing the instructions. Although Gelfand does not disclose the medium, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to include the medium since it is old and well known that a processor cannot function without first being programmed by a medium containing the necessary instructions.

Regarding claim 45, Gelfand, as modified above, does not disclose a display configured to display a spontaneous intrinsic cycle of a subject. However Halperin discloses displaying ECG on a monitor to ascertain a true ECG signal (Col. 11, lines 50-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to include a visual display of cardiac cycles in order to help process CPR-affected ECG signals. Furthermore, a visual display will inherently indicate a favorable time to deliver a chest compression since teaches that any period of time except for the T-wave is a safe time to deliver a compression.

(10) Response to Argument

Applicant's arguments filed 5/29/2007 have been fully considered but they are not persuasive. The applicant argues that Gelfand teaches timing compressions that apparently coincide with the portion in Link that resulted in ventricular fibrillation (the upslope of the T-wave), and, as such, Gelfand teaches away from avoiding chest wall compressions during this portion of the cardiac cycle. The Examiner respectfully disagrees. While it may be true that Gelfand teaches that compressions might coincide with the upslope of the T-wave, Gelfand never specifically teaches delivering compressions during the upslope, and therefore, cannot directly teach away from

avoiding CPR compressions on the upslope of the T-wave; this is merely a portion where the compression **could** be delivered. Instead, Gelfand generally teaches that the timing of the compressions is chosen to provide the best possible assistance to a weakened heart, thus improving cardiac function (see paragraph abridging cols. 9 and 10), which is also the goal of the applicant's current invention (see independent claim 26). Gelfand states that the compression will be delivered at a "predetermined period of time following the QRS complex wave of the ECG signal," but is silent as to the exact timing (Col. 9, lines 5-8). In other words, Gelfand teaches that the compression may be delivered anytime after the QRS complex, including the ST segment, upslope and downslope of the T-wave and the U-wave, as long as the timing results in the best assistance to the heart. Therefore, one of ordinary skill in the art would be motivated to determine what the optimal timing may be with more specificity.

The secondary reference of Link was presented to show that low impact chest compressions should be avoided during the upslope of the T-wave since this results in the occurrence of ventricular fibrillation (see Experimental models section). It is the Examiner's continued position that the compressions delivered during CPR are inherently low-impact chest blows, especially since it is well known in the art that CPR done properly may result in broken ribs and/or a broken sternum. Therefore, it is clear from Link that cardiac function would not be improved by compressing the heart during the upslope of the T-wave; in fact, this may cause further damage to the heart and the patient's health. Therefore, based on Link's teaching of avoiding chest compressions during the upslope of the T-wave, it would have been obvious to one of ordinary skill in

Art Unit: 3766

that art to modify Gelfand to provide compressions following the QRS complex that did not coincide with the upslope of the T-wave in order to improve cardiac function.

Applicant further argues that there are no reasons to combine Link and Gelfand. However, as described above, both references deal with the timing of low-impact compressions of the heart and the impact these compressions have on the heart's function. While Link discloses that commotio cordis is prevalent in healthy individuals, there is no discussion in the Experimental models on the condition of the patient's hearts. Therefore, the test can be taken as a generic showing that compressions to ANY heart during the upslope of the T-wave may result in ventricular fibrillation. Regardless, one of ordinary skill in the art would reason that if the induction of ventricular fibrillation is at all possible by compressing the heart during the upslope of the T-wave, this specific timing should be avoided as a precaution.

Therefore, the 35 U.S.C. 103(a) rejection of claims 26-28, 41-43, 49 and 51 as being unpatentable over Gelfand in view of Link is still considered proper. Regarding claims 31-33, 44, 45, 52 and 54-57, the applicant merely relied on the arguments presented against Gelfand and Link. As a result, the 35 U.S.C. 103(a) rejection of claims 31-33, 44, 45, 52 and 54-57 as being unpatentable over Gelfand in view of Link and further in view of Halperin et al. is still considered proper as well.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Art Unit: 3766

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Eric Bertram



Conferees:

Stephen Garbe 

Carl Layno



CARL LAYNO
PRIMARY EXAMINER